Standard Operating Procedure
For

Internal Quality Assurance Audit

Revision 4

Laboratory Services Division

Office of Environmental Assessment

Louisiana Department of Environmental Quality

Development Team: Jacqueline A. Prudente Date: 5-6-08
Jacqueline A. Prudente, Ph.D., Assessor

Development Team: Paul Bergeron Date: 5-6-08
Paul Bergeron, LELAP Supervisor

Development Team: Date: 5-6-08
Elaine Sorbet, QA Officer

Development Team: Date: 5-6-2008
Melvin C. Mitchell, Sr., Division Administrator

Please Note: The official version of this document is maintained on the LDEQ Intranet. Copies, whether in electronic or printed form, are not official and should be verified for currency against the official document on the Intranet. The Control Header of the SOP will be used for comparison to the official document.

Document Review and Revision Record

Note: Actions older than 5 years may be removed from this record

Approval Date	Revision No.	Record of Activity
2/09/01	0	Initial document approved.
03/15/05	1	Changed Administrator
04/13/06	2	Changed to new format
05/11/2007	3	Name change for LELAP Supervisor and technical changes related to NELAC and TNI
05/06/2008	**4**	**Name change for one Development team member and minor changes related to document format**

Table of Contents

STANDARD OPERATING PROCEDURE for

INTERNAL QUALITY ASSURANCE AUDIT

SOP #LELAP QA-001

1.0 Purpose

The purpose of this standard operating procedure (SOP) is to establish requirements for conducting an internal quality assurance (QA) audit of the Louisiana Environmental Laboratory Accreditation Program (LELAP). The quality assurance audit is essential to demonstrate the LELAP Assessors' adherence to the established LELAP procedures, LAC 33:I.Chapter 45 through Chapter 59 and the NELAC Standard when appropriate. The purposes of the internal audit are:

1.1 To identify areas of improvement.

1.2 To provide management with an assessment of the quality of results produced by the LELAP Assessors and Program Analyst.

1.3 To demonstrate that LELAP is assessing the effectiveness of the program.

1.4 To provide the Administrator with information to aid in developing effective corrective action when audits identify areas of concern.

2.0 LELAP Quality Assurance Coordinator

2.1 The LELAP Quality Assurance Coordinator (QAC) shall evaluate the LELAP program annually to determine if its objectives are being achieved. This review shall determine the effectiveness of the program and identify areas of concern.

2.2 The QAC must have direct access to the highest level of management for decisions regarding the LELAP quality assurance policies and resources.

2.3 The LELAP QAC shall have independent authority regarding quality assurance oversight and implementation of the quality assurance plan.

2.4 The LELAP QAC shall be responsible for conducting annual reviews and revising as necessary the LELAP SOPs and Quality Assurance Plan.

2.5 Additionally, the QAC shall review and revise the SOPs and QAP any time it becomes apparent that LELAP must update its day-to-day operations.

2.6 The LELAP QAC shall conduct an annual audit of the LELAP program to identify areas of concern.

3.0 Internal Audit

3.1 The LELAP QAC shall notify the program Administrator of a pending internal audit within 10 working days of the required audit.

3.2 The program Administrator shall notify the LELAP staff in writing of the pending internal audit. At that time the staff shall be notified of the level of participation that is required for each member.

3.3 LELAP QAC shall conduct a review of Laboratory records as found in the LELAP program. LELAP Assessors shall be available to assist with the file review using the Records Review Form (Appendix A). The records review shall be completed within 4 working days of the initial start of the internal audit.

3.4 The Records Review will identify compliance with stipulated time frames, regulations, and completeness of documentation.

3.5 Interviews of the LELAP Assessors and Program Analyst shall be conducted by the LELAP QAC to demonstrate the program's staff understanding of the program, regulations, and SOPs.

4.0 Quality Assurance Audit Report

4.1 Within 15 working days of completion of the internal quality assurance audit, the QAC shall submit to the program Administrator a report identifying areas of concern and possible corrective action.

4.2 The report shall identify the following areas:

4.2.1 Improvements if applicable

4.2.2 Findings or areas of concern

4.2.3 Staffing

4.2.4 Conclusions and corrective action.

4.3 The LELAP QAC shall ensure the implementation of approved corrective actions within 30 days of notification. The QAC shall conduct a follow-up audit to document the implementation of corrective action.

ATTACHMENT A

Records Review

Please review each file as assigned and complete this questionnaire for each assigned laboratory. Indicate the documents found in each of the records reviewed and include the date of the document or the date received as appropriate. Please comment on any documents that are missing. Indicate in the comments section whenever the Laboratory records are not in chronological order and in the appropriate file folder types.

Lab ID: _____Laboratory Name: _____

Review Completed By: _____

1. Is the application and fee package complete? _____

2. Was the laboratory notified that the application and fee package was received by LELAP? _____

3. Was the laboratory notified of any deficiencies found in the application package? _____

4. Did the laboratory respond to the deficiencies in the application in the required timeframe? _____

5. Did the laboratory submit (2) PT studies? _____

6. Has the Department received documentation of changes in ownership, name, location, key personnel, methodology used or any significant changes that would affect performance of analysis? _____

7. Did LELAP notify the laboratory in writing of the proposed assessment date?

---

8. Is the signed assessment report with associated documents bound and located in the correct file folder? _____

9. If the assessment report listed deficiencies, did the laboratory provide a corrective action plan (cap) or completed corrective action documents (CCAD) within the required thirty day? _____

10. Did LELAP respond to the corrective action plan within the 30 days of receipt of the CAP or CCAD? _____

---

11. Did LELAP notify the laboratory when all deficiencies identified in the assessment report were satisfactorily completed? _____

12. If the laboratory was denied accreditation, did LELAP notify the laboratory of continued non-compliance? _____

13. Has LELAP received two PT studies per year for the laboratory _____

14. Did the laboratory submit corrective action PT results for "unacceptable" results? _____

15. Did LELAP notify the laboratory if corrective action PT results were not submitted?

COMMENTS:_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____